PHS PATENT LICENSE AGREEMENT-EXCLUSIVE

For PHS internal use only:

Patent License Number: _____

Serial Numbers of Licensed Patents:_____

Licensee: _____ CRADA Number (if applicable): _____

Additional Remarks:

_____

_____

_____

Public Health Service

PATENT LICENSE AGREEMENT - EXCLUSIVE

This Patent License Agreement, hereinafter referred to as the "Agreement," consists of this Cover Page, an attached Agreement, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Modifications), Appendix E (Benchmarks), and Appendix F (Commercial Development Plan). The Parties to this Agreement are:

1. The National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "PHS," agencies of the United States Public Health Service within the Department of Health and Human Services ("DHHS"); and

2. The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "Licensee." PHS and Licensee agree as follows:

1. BACKGROUND

1.01 In the course of conducting biomedical and behavioral research, PHS investigators made inventions that may have commercial applicability.

1.02 By assignment of rights from PHS employees and other inventors, DHHS, on behalf of the United States Government, owns intellectual property rights claimed in any United States and foreign patent applications or patents corresponding to the assigned inventions. DHHS also owns any tangible embodiments of these inventions actually reduced to practice by PHS.

1.03 The Assistant Secretary for Health of DHHS has delegated to PHS the authority to enter into this Agreement for the licensing of rights to these inventions under 35 USC §§200-212, the Federal Technology Transfer Act of 1986, 15 USC §3710a, and/or the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.04 PHS desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.05 Licensee desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.01 "Benchmarks" mean the performance milestones that are set forth in Appendix E.

2.02 "Commercial Development Plan" means the written commercialization plan attached as Appendix F.

2.03 "First Commercial Sale" means the initial transfer by or on behalf of Licensee or its sublicensees of Licensed Products or the initial practice of a Licensed Process by or on behalf of Licensee or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.

2.04 "Government" means the Government of the United States of America.

2.05 "Licensed Fields of Use" means the fields of use identified in Appendix B. 2.06"Licensed Patent Rights" shall mean:

a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; and iv) any reissues, reexaminations, and extensions of all such patents;

c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign applications and patents to a) and b) above, including those listed in Appendix A. Licensed Patent Rights shall not include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in a) above.

2.07 "Licensed Process(es)" means processes which, in the course of being practiced would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.08 "Licensed Product(s)" means tangible materials which, in the course of manufacture, use, or sale would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.09 "Licensed Territory" means the geographical area identified in Appendix B.

2.10 "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of Licensee or its sublicensees, and from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by Licensee, or sublicensees, and on its payroll, or for the cost of collections.

2.11 "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

2.12 "Research License" means a nontransferable, nonexclusive license to make and to use the Licensed Products or Licensed Processes as defined by the Licensed Patent Rights for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

3. GRANT OF RIGHTS

3.01 PHS hereby grants and Licensee accepts, subject to the terms and conditions of this Agreement, an exclusive license under the Licensed Patent Rights in the Licensed Territory to make and have made, to

use and have used, and to sell and have sold any Licensed Products in the Licensed Fields of Use and to practice and have practiced any Licensed Processes in the Licensed Fields of Use.

3.02 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of PHS other than Licensed Patent Rights regardless of whether such patents are dominant or subordinate to Licensed Patent Rights.

4. SUBLICENSING

4.01 Upon written approval by PHS, which approval will not be unreasonably withheld, Licensee may enter into sublicensing agreements under the Licensed Patent Rights.

4.02 Licensee agrees that any sublicenses granted by it shall provide that the obligations to PHS of Paragraphs 5.01-5.04, 8.01, 10.01, 10.02, 12.05 and 13.07-13.09 of this Agreement shall be binding upon the sublicensee as if it were a party to this Agreement. Licensee further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.03 Any sublicenses granted by Licensee shall provide for the termination of the sublicense, or the conversion to a license directly between such sublicensees and PHS, at the option of the sublicensee, upon termination of this Agreement under Article 13. Such conversion is subject to PHS approval and contingent upon acceptance by the sublicensee of the remaining provisions of this Agreement.

4.04 Licensee agrees to forward to PHS a copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of such agreement. To the extent permitted by law, PHS agrees to maintain each such sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.01 PHS reserves on behalf of the Government an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the Licensed Patent Rights throughout the world by or on behalf of the Government and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the Government is a signatory. Prior to the First Commercial Sale, Licensee agrees to provide PHS reasonable quantities of Licensed Products or materials made through the Licensed Processes for PHS research use.

5.02 Licensee agrees that products used or sold in the United States embodying Licensed Products or produced through use of Licensed Processes shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from PHS.

5.03 Licensee acknowledges that PHS may enter into future Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this Agreement. Licensee agrees not to unreasonably deny requests for a Research License from such future collaborators with PHS when acquiring such rights is necessary in order to make a CRADA project feasible. Licensee may request an opportunity to join as a party to the proposed CRADA.

5.04 In addition to the reserved license of Paragraph 5.01 above, PHS reserves the right to grant such nonexclusive Research Licenses directly or to require Licensee to grant nonexclusive Research Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, PHS shall consult with Licensee before granting to commercial entities a Research License or providing to them research samples of the materials.

6. ROYALTIES AND REIMBURSEMENT

6.01 Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this Agreement becomes effective.

6.02 Licensee agrees to pay to PHS a nonrefundable minimum annual royalty as set forth in Appendix C. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year. The minimum annual royalty due for the first calendar year of this Agreement may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1.

6.03 Licensee agrees to pay PHS earned royalties as set forth in Appendix C.

6.04 Licensee agrees to pay PHS benchmark royalties as set forth in Appendix C.

6.05 Licensee agrees to pay PHS sublicensing royalties as set forth in Appendix C.

6.06 A claim of a patent or patent application licensed under this Agreement shall cease to fall within the Licensed Patent Rights for the purpose of computing the minimum annual royalty and earned royalty payments in any given country on the earliest of the dates that a) the claim has been abandoned but not continued, b) the patent expires or irrevocably lapses, or c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.07 No multiple royalties shall be payable because any Licensed Products or Licensed Processes are covered by more than one of the Licensed Patent Rights.

6.08 On sales of Licensed Products by Licensee to sublicensees or affiliated parties or on sales made in other than an arm's-length transaction, the value of the Net Sales attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.

6.09 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights incurred by PHS prior to the effective date of this Agreement, Licensee shall pay to PHS, as an additional royalty, within sixty (60) days of PHS's submission of a statement and request for payment to Licensee, an amount equivalent to such patent expenses previously incurred by PHS.

6.10 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights incurred by PHS on or after the effective date of this Agreement, PHS, at its sole option, may require Licensee:

1. to pay PHS on an annual basis, within sixty (60) days of PHS's submission of a statement and request for payment, a royalty amount equivalent to all such patent expenses incurred during the previous calendar year(s); or

2. to pay such expenses directly to the law firm employed by PHS to handle such functions. However, in such event, PHS and not Licensee shall be the client of such law firm.

Under exceptional circumstances, Licensee may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the Licensed Patent Rights. In that event, Licensee shall directly pay the attorneys or agents engaged to

prepare, file, prosecute or maintain such patent applications or patents and shall provide to PHS copies of each invoice associated with such services as well as documentation that such invoices have been paid.

6.11 Licensee may elect to surrender its rights in any country of the Licensed Territory under any Licensed Patent Rights upon sixty (60) days written notice to PHS and owe no payment obligation under Article 6.10 for patent-related expenses incurred in that country after the effective date of such written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.01 Except as otherwise provided in this Article 7, PHS agrees to take responsibility for, but to consult with, the Licensee in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall furnish copies of relevant patent-related documents to Licensee.

7.02 Upon PHS's written request, Licensee shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall on an ongoing basis promptly furnish copies of all patent-related documents to PHS. In such event, Licensee shall, subject to the prior approval of PHS, select registered patent attorneys or patent agents to provide such services on behalf of Licensee and PHS. PHS shall provide appropriate powers of attorney and other documents necessary to undertake such actions to the patent attorneys or patent agents providing such services. Licensee and its attorneys or agents shall consult with PHS in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the Licensed Patent Rights and shall provide PHS sufficient opportunity to comment on any document that Licensee intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.03 At any time, PHS may provide Licensee with written notice that PHS wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights. If PHS elects to assume such responsibilities, Licensee agrees to cooperate fully with PHS, its attorneys and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and to provide PHS with complete copies of any and all documents or other materials that PHS deems necessary to undertake such responsibilities. Licensee shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of PHS's choice.

7.04 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the Licensed Patent Rights and permit each other to provide comments and suggestions with respect to the preparation, filing, and prosecution of Licensed Patent Rights, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.01 Licensee agrees to keep accurate and correct records of Licensed Products made, used, or sold and Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due PHS. Such records shall be retained for at least five (5) years following a given reporting period. They shall be available during normal business hours for inspection at the expense of PHS by an accountant or other designated auditor selected by PHS for the sole purpose of verifying reports and payments hereunder. The accountant or auditor shall only disclose to PHS information relating to the accuracy of reports and payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then Licensee shall reimburse PHS for the cost of the inspection at the time Licensee pays the unreported royalties, including any late charges as required by Paragraph 9.08 of this Agreement. All payments required under this Paragraph shall be due within thirty (30) days of the date PHS provides Licensee notice of the payment due.

8.02 Licensee agrees to conduct an independent audit of sales and royalties at least every two years if annual sales of the Licensed Product or Licensed Processes are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of Licensee during the audit period, the amount of funds owed to the Government under this Agreement, and whether the amount owed has been paid to the Government and is reflected in the records of the Licensee. A report by the auditor shall be submitted promptly to PHS on completion. Licensee shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.01 Prior to signing this Agreement, Licensee has provided to PHS the Commercial Development Plan at Appendix F, under which Licensee intends to bring the subject matter of the Licensed Patent Rights to the point of Practical Application. This Commercial Development Plan is hereby incorporated by reference into this Agreement. Based on this plan, performance Benchmarks are determined as specified in Appendix E.

9.02 Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, and sales during the preceding calendar year, as well as plans for the present calendar year. PHS also encourages these reports to include information on any of Licensee's public service activities that relate to the Licensed Patent Rights.

If reported progress differs from that projected in the Commercial Development Plan and Benchmarks, Licensee shall explain the reasons for such differences. In any such annual report, Licensee may propose amendments to the Commercial Development Plan, acceptance of which by PHS may not be denied unreasonably. Licensee agrees to provide any additional information reasonably required by PHS to evaluate Licensee's performance under this Agreement. Licensee may amend the Benchmarks at any time upon written consent by PHS. PHS shall not unreasonably withhold approval of any request of Licensee to extend the time periods of this schedule if such request is supported by a reasonable showing by Licensee of diligence in its performance under the Commercial Development Plan and toward bringing the Licensed Products to the point of practical application as defined in 37 CFR 404.3(d).

Licensee shall amend the Commercial Development Plan and Benchmarks at the request of PHS to address any Licensed Fields of Use not specifically addressed in the plan originally submitted.

9.03 Licensee shall report to PHS the date of the First Commercial Sale in each country in the Licensed Territory within thirty (30) days of such occurrence.

9.04 Licensee shall submit to PHS within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each such royalty report, Licensee shall submit payment of the earned royalties due. If no earned royalties are due to PHS for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of Licensee and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine Net Sales made under Article 6 to determine royalties due.

9.05 Licensee agrees to forward semi-annually to PHS a copy of such reports received by Licensee from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to PHS by Licensee for activities under the sublicense.

9.06 Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in The Wall Street Journal on the day that the payment is due.

All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, for FDA or NIH licenses to the National Institutes of Health, P.O. Box 360120, Pittsburgh, Pennsylvania 15251-6120 or for CDC licenses to the Centers for Disease Control and Prevention, CDC Financial Management Office, 255 East Paces Ferry Road, NE (MS-E12), Atlanta, Georgia 30305. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by Licensee. The royalty report required by Paragraph 9.04 of this Agreement shall accompany each such payment and a copy of such report shall also be mailed to PHS at its address for notices indicated on the "Signature Page" of this Agreement.

9.07 Licensee shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax and be responsible for all filings with appropriate agencies of foreign governments.

9.08 Late charges will be assessed by PHS as additional royalties on any overdue payments at a rate of one (1) percent per month compounded monthly. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment.

9.09 All plans and reports required by this Article 9 and marked "confidential" by Licensee shall, to the extent permitted by law, be treated by PHS as commercial and financial information obtained from a person and as privileged and confidential and any proposed disclosure of such records by the PHS under the Freedom of Information Act, 5 U.S.C. § 552 shall be subject to the predisclosure notification requirements of 45 CFR § 5.65(d).

10. PERFORMANCE

10.01 Licensee shall use its reasonable best efforts to bring the License Products and Licensed Processes to Practical Application. "Reasonable best efforts" for the purposes of this provision shall include adherence to the Commercial Development Plan at Appendix F and performance of the Benchmarks at Appendix E. The efforts of a sublicensee shall be considered the efforts of Licensee.

10.02 Upon the First Commercial Sale, until the expiration of this Agreement, Licensee shall use its reasonable best efforts to make Licensed Products and Licensed Processes reasonably accessible to the United States public.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.01 PHS and Licensee agree to notify each other promptly of each infringement or possible infringement of the Licensed Patent Rights, as well as any facts which may affect the validity, scope, or enforceability of the Licensed Patent Rights of which either Party becomes aware.

11.02 Pursuant to this Agreement and the provisions of Chapter 29 of title 35, United States Code, Licensee may a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the Licensed Patent Rights; b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for infringement of the Licensed Patent Rights provided, however, that PHS and appropriate Government authorities shall have the first right to take such actions. If Licensee desires to initiate a suit for patent infringement, Licensee shall notify PHS in writing. If PHS does not notify Licensee of its intent to pursue legal action within ninety (90) days, Licensee will be free to initiate suit. PHS shall have a continuing right to intervene in such suit.

Licensee shall take no action to compel the Government either to initiate or to join in any such suit for patent infringement. Licensee may request the Government to initiate or join in any such suit if necessary to avoid dismissal of the suit. Should the Government be made a party to any such suit, Licensee shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of such motion or other action, including any and all costs incurred by the Government in opposing any such motion or other action.

In all cases, Licensee agrees to keep PHS reasonably apprised of the status and progress of any litigation. Before Licensee commences an infringement action, Licensee shall notify PHS and give careful consideration to the views of PHS and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.03 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the Licensed Patent Rights shall be brought against Licensee or raised by way of counterclaim or affirmative defense in an infringement suit brought by Licensee under Paragraph 11.02, pursuant to this Agreement and the provisions of Chapter 29 of Title 35, United States Code or other statutes, Licensee may

1.defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the Licensed Patent Rights;

2.in any such suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement;

3. and settle any claim or suit for declaratory judgment involving the Licensed Patent Rights—provided, however, that PHS and appropriate Government authorities shall have the first right to take such actions and shall have a continuing right to intervene in such suit. If PHS does not notify Licensee of its intent to respond to the legal action within a reasonable time, Licensee will be free to do so.

Licensee shall take no action to compel the Government either to initiate or to join in any such declaratory judgment action. Licensee may request the Government to initiate or to join any such suit if necessary to avoid dismissal of the suit. Should the Government be made a party to any such suit by motion or any other action of Licensee, Licensee shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of such motion or other action. If Licensee elects not to defend against such declaratory judgment action, PHS, at its option, may do so at its own expense.

In all cases, Licensee agrees to keep PHS reasonably apprised of the status and progress of any litigation. Before Licensee commences an infringement action, Licensee shall notify PHS and give careful consideration to the views of PHS and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.04 In any action under Paragraphs 11.02 or 11.03, the expenses including costs, fees, attorney fees, and disbursements, shall be paid by Licensee. Up to fifty percent (50%) of such expenses may be credited against the royalties payable to PHS under Paragraph 6.03 under the Licensed Patent Rights in the country in which such a suit is filed. In the event that fifty percent (50%) of such expenses exceed the amount of royalties payable by Licensee in any calendar year, the expenses in excess may be carried over as a credit on the same basis into succeeding calendar years.

A credit against litigation expenses, however, may not reduce the royalties due in any calendar year to less than the minimum annual royalty. Any recovery made by Licensee, through court judgment or settlement, first shall be applied to reimburse PHS for royalties withheld as a credit against litigation expenses and then to reimburse Licensee for its litigation expense. Any remaining recoveries shall be shared equally by Licensee and PHS. PHS shall cooperate fully with Licensee in connection with any action under

Paragraphs 11.02 or 11.03. PHS agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by Licensee.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.01 PHS offers no warranties other than those specified in Article 1. PHS does not warrant the validity of the Licensed Patent Rights and makes no representations whatsoever with regard to the scope of the Licensed Patent Rights, or that the Licensed Patent Rights may be exploited without infringing other patents or other intellectual property rights of third parties.

12.02 PHS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS.

12.03 PHS does not represent that it will commence legal actions against third parties infringing the Licensed Patent Rights.

12.04 Licensee shall indemnify and hold PHS, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by or on behalf of Licensee, its sublicensees, directors, employees, or third parties of any Licensed Patent Rights, or b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or materials by Licensee, or other products or processes developed in connection with or arising out of the Licensed Patent Rights. Licensee agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.01 This Agreement is effective when signed by all parties and shall extend to the expiration of the last to expire of the Licensed Patent Rights unless sooner terminated as provided in this Article 13.

13.02 In the event that Licensee is in default in the performance of any material obligations under this Agreement, including but not limited to the obligations listed in Article 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, PHS may terminate this Agreement by written notice.

13.03 In the event that Licensee becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, Licensee shall immediately notify PHS in writing.

13.04 Licensee shall have a unilateral right to terminate this Agreement and/or any licenses in any country by giving PHS sixty (60) days written notice to that effect.

13.05 PHS shall specifically have the right to terminate or modify, at its option, this Agreement, if PHS determines that the Licensee:

1. is not executing the Commercial Development Plan submitted with its request for a license and the Licensee cannot otherwise demonstrate to PHS's satisfaction that the Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the Licensed Products or Licensed Processes;

2. has not achieved the Benchmarks as may be modified under Paragraph 9.02;

3. has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license agreement;

4. has committed a material breach of a covenant or agreement contained in the license;

5. is not keeping Licensed Products or Licensed Processes reasonably available to the public after commercial use commences;

6. cannot reasonably satisfy unmet health and safety needs; or

7. cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived.

In making this determination, PHS will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by Licensee under Paragraph 9.02. Prior to invoking this right, PHS shall give written notice to Licensee providing Licensee specific notice of, and a ninety (90) day opportunity to respond to, PHS's concerns as to the previous items 1) to 7). If Licensee fails to alleviate PHS's concerns as to the previous items 1) to 7) or fails to initiate corrective action to PHS's satisfaction, PHS may terminate this Agreement.

13.06 When the public health and safety so require, and after written notice to Licensee providing Licensee a sixty (60) day opportunity to respond, PHS shall have the right to require Licensee to grant sublicenses to responsible applicants, on reasonable terms, in any Licensed Fields of Use under the Licensed Patent Rights, unless Licensee can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the Licensed Patent Rights. PHS will not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with Licensee.

13.07 PHS reserves the right according to 35 USC §209(f)(4) to terminate or modify this Agreement if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by Licensee.

13.08 Within thirty (30) days of receipt of written notice of PHS's unilateral decision to modify or terminate this Agreement, Licensee may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated PHS official. The decision of the designated PHS official shall be the final agency decision. Licensee may thereafter exercise any and all administrative or judicial remedies that may be available.

13.09 Within ninety (90) days of termination of this Agreement under this Article 13 or expiration under Paragraph 3.02, a final report shall be submitted by Licensee. Any royalty payments, including those related to patent expense, due to PHS shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with PHS pursuant to Paragraph 4.03.

14. GENERAL PROVISIONS

14.01 Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of the Government to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by the Government or excuse a similar subsequent failure to perform any such term or condition by Licensee.

14.02 This Agreement constitutes the entire agreement between the Parties relating to the subject matter of the Licensed Patent Rights, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this Agreement.

14.03 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law such determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

14.04 If either Party desires a modification to this Agreement, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this Agreement or their designees.

14.05 The construction, validity, performance, and effect of this Agreement shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.06 All notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party, and shall be effective as of the date of the postmark of such notice.

14.07 This Agreement shall not be assigned by Licensee except a) with the prior written consent of PHS, such consent not to be withheld unreasonably; or b) as part of a sale or transfer of substantially the entire business of Licensee relating to operations which concern this Agreement. Licensee shall notify PHS within ten (10) days of any assignment of this Agreement by Licensee.

14.08 Licensee agrees in its use of any PHS-supplied materials to comply with all applicable statutes, regulations, and guidelines, including Public Health Service and National Institutes of Health regulations and guidelines. Licensee agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. Licensee agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying PHS, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to PHS of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

14.09 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. PHS neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 Licensee agrees to mark the Licensed Products or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All Licensed Products manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve PHS patent rights in such countries.

14.11 By entering into this Agreement, PHS does not directly or indirectly endorse any product or service provided, or to be provided, by Licensee whether directly or indirectly related to this Agreement. Licensee shall not state or imply that this Agreement is an endorsement by the Government, PHS, any other Government organizational unit, or any Government employee. Additionally, Licensee shall not use the

names of NIH, CDC, PHS, or DHHS or the Government or their employees in any advertising, promotional, or sales literature without the prior written consent of PHS.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this Agreement or a breach of this Agreement, except for appeals of modifications or termination decisions provided for in Article 13. Licensee agrees first to appeal any such unsettled claims or controversies to the designated PHS official, or designee, whose decision shall be considered the final agency decision. Thereafter, Licensee may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 4.03, 8.01, 9.06-9.08, 12.01-12.05, 13.08, 13.09, and 14.12 of this Agreement shall survive termination of this Agreement.

SIGNATURE PAGE

For PHS:

_____ Date: _____
Barbara McGarey, JD
Deputy Director
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices: Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892

For Licensee:

(Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of Licensee made or referred to in this document are truthful and accurate.):

_____
Name of Licensee

_____ Date _____
Signature of Authorized Official
Printed Name and Title _____

Mailing Address for Notices:

_____

_____

_____

APPENDIX A -Patent(s) or Patent Application(s)

APPENDIX B - Licensed Fields of Use and Territory

APPENDIX C - Royalties

Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty in the amount of_____.

Licensee agrees to pay to PHS a nonrefundable minimum annual royalty in the amount of_____.

Licensee agrees to pay PHS earned royalties on Net Sales as follows:

Licensee agrees to pay PHS benchmark royalties as follows: Licensee agrees to pay PHS sublicensing royalties as follows:

APPENDIX D - Modifications

PHS and Licensee agree to the following modifications to the Articles and Paragraphs of this Agreement:

APPENDIX E - Benchmarks and Performance

Licensee agrees to the following Benchmarks for its performance under this Agreement and, within ten (10) days of achieving a Benchmark, shall notify PHS that the Benchmark has been achieved.

APPENDIX F - Commercial Development Plan